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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,892	03/21/2005	Yoshiyuki Ueno	IPE-051	9982

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EXAMINER	
SYKES, ALTREV C	
ART UNIT	PAPER NUMBER
1798	

MAIL DATE	DELIVERY MODE
10/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,892	UENO ET AL.	
	Examiner	Art Unit	
	ALTREV C. SYKES	1798	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,13,15 and 17-40* is/are pending in the application.

4a) Of the above claim(s) *19-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-10,12,13,15,17 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20100528*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment to the claims filed August 2, 2010 is acknowledged by examiner and has been entered. Claim 1 has been amended. Claims 11, 14, and 16 have been cancelled. Claims 1-10, 12-13, 15, 17 and 40 are pending examination on the merits.

Response to Arguments

2. Applicant's arguments filed August 2, 2010, with respect to claims 1-10, 12-13, 15-, 17 and 40 have been fully considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-10, 12-13, 15, 17 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onodera et al. (US 5,407,581) in view of Kozawa et al. (US 6,605,218)

Regarding claims 1, 10, and 40 Onodera et al. discloses a filter medium for treating a blood material. (See Col 1, lines 8-10) Onodera et al. discloses the surface of the porous element of the filter medium can be modified with a compound by conventional techniques, such as covalent bonding or ionic bonding, radiation-graft copolymerization or plasma treatment, physical adsorption, embedding, or precipitate immobilization. (See Col 15, lines 64-68) Onodera et al. discloses in addition to the negative functional groups, positive functional groups and/or nonionic functional groups may coexist at or on a surface portion of the filter medium. Examples of nonionic functional groups include: nonionic hydrophilic functional groups, such as a polyethylene glycol chain. (See Col 11, lines 60-68 and Col 12, lines 1-15) Examiner notes that Onodera et al. teaches the use of cationic, anionic, and/or nonionic polymers for use with the filter medium. (See Col 12, lines 50-68 and Col 16, lines 9-12 and 35-40) Onodera et al. discloses the filter medium may also be a hollow fiber. (See Col 4, all) While applicant does not use the term "precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) Therefore, examiner notes that a hollow fiber membrane would be exemplary of a "precursor" substrate as claimed by applicant.

Kozawa et al. discloses a dialyzer for blood treatment which comprises a semipermeable membrane. (See Abstract) Kozawa et al. discloses the semipermeable membrane comprises a hydrophobic polymer and a hydrophilic polymer. (See Col 1, lines 58-61) Kozawa et al. discloses the hydrophilic polymer may be polyethylene glycol, polyvinyl pyrrolidone or a combination thereof. Polyvinyl pyrrolidone (PVP) is preferred since it is relatively high in industrial availability. (See Col 2, lines 40-50) Kozawa et al. discloses the semipermeable membrane may be a hollow fiber membrane. (See Col 4, lines 3-5) Kozawa et al. discloses the semipermeable membrane may be used as an artificial kidney. The membrane be subjected to a cross-linking treatment with gamma-ray irradiation, etc. (See Col 4, lines 17-23 and 30-40)

As Onodera and Kozawa et al. are both directed to filter mediums for treating blood materials, the art is analogous. Therefore, it would have been obvious to one of ordinary skill in the art to substitute one hydrophilic polymer for another, where the polymer would function in the same desired capacity as the original polymer, motivated by expected results since the prior art teaches that polyethylene glycol and PVP may be used interchangeably as the hydrophilic polymers for producing hollow fiber membranes. One of ordinary skill in the art would have also been motivated to utilize the PVP as taught by Kozawa et al. in place of the polyethylene glycol as disclosed by Onodera motivated by the preferred desire to utilize a hydrophilic polymer which is relatively high in industrial availability. (See Kozawa Col 2, lines 45-47)

Further regarding claims 1 and 10 examiner notes that because the polymer is being immobilized on the surface of the porous element, one of ordinary skill in the art would have been easily motivated to minimize the amount of unbonded hydrophilic material since bonding is preferred thereby improving the functionality of the membrane to treat blood material. (See Onodera Col 2, lines 15-25)

Regarding claims 2-5, examiner maintains the position as set forth above. Further, examiner notes that this claim is directed to process steps for obtaining the modified substrate. As the modified substrate of Onodera et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can be obtained in the same manner as that claimed by applicant. Further, applicant is reminded that the patentability of a product does not depend on it's method of production. Therefore, the use of an aqueous solution of the hydrophilic (and a solution containing an antioxidant) is deemed moot since the limitations are again directed to a method of producing the modified substrate. Finally, examiner notes that claim 1 from which claim 2 depends does not recite that the hydrophilic polymer is in solution at all.

Regarding claim 6, one of ordinary skill in the art would expect that *less than* 15 weight percent of the hydrophilic polymer *would not* be covalently bonded to the surface since covalent bonding is taught to be a preferred method for providing the hydrophilic

polymer to the surface. Applicant discloses the surface hydrophilic polymer ratio is a parameter representing the degree of hydrophilicity on the surface of the modified substrate. (See [0017] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are preferred because those groups or chains have excellent effects especially on filter media for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) Kozawa et al. discloses the use of PVP provides a membrane improved in water permeability and dialyze performance. (See Col 1, lines 45-55) Therefore, one of ordinary skill in the art would expect that the surface hydrophilic polymer ratio of the Onodera and Kozawa et al. modified substrate would be at least 20 weight percent since the materials used to provide the modified substrate would determine this parameter.

Regarding claim 7, Kozawa et al. discloses the hydrophilic polymer may be polyethylene glycol, polyvinyl pyrrolidone or a combination thereof. (See Col 2, lines 40-50)

Regarding claims 8-9 and 12 examiner maintains the position as set forth above wherein functional groups may coexist at or on the surface with the hydrophilic polymer. (See Col 11, lines 60-68 and Col 12, lines 1-15) Onodera et al. discloses examples of positive functional groups include ethyleneimine, and oligomers and polymers which have any of the above-mentioned monomers as monomer units thereof. (See Col 12, lines 50-68) Examiner therefore equates the use of ethyleneimine polymers of Onodera et al. to

cationic hydrophilic polymers. (See [0028] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are preferred because those groups or chains have excellent effects especially on filter media for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) With further respect to claim 9, Onodera et al. further discloses when the substrate is used for an adsorptive filter membrane, the substrate may comprise a negatively charged ligand such as dextran sulfate. (See Col 35, lines 52-59 and Col 36, lines 67-68 and Col 38, lines 20-23) It is to be noted that applicant discloses an anionic polymer such as dextran sulfate (a polymer derived from the living body) may be used. (See instant specification [0028] and [0030]) As such, examiner notes that Onodera teaches a modified substrate having a plurality of hydrophilic polymers thereon including cationic, nonionic, *and/or* anionic hydrophilic polymers.

Regarding claim 13, as the modified substrate of Onodera et al. and Kozawa et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can function in the same capacity as that claimed by applicant with respect to the adsorptivity of interleukin-6. Further, examiner notes that Onodera et al. discloses an apparatus containing the adsorptive filter membrane which can be used to remove interleukin from a blood material. (See Col 49, lines 22-35)

Regarding claim 15, Onodera et al. discloses examples of materials to be used for preparing polymeric, porous element of the filter medium include polymeric compounds which are obtained by polymerization of methacrylate derivatives, such as methyl methacrylate. (See Col 15, lines 6-15) Kozawa et al. discloses the hydrophobic polymer may be a polysulfonic resin. (See Col 3, lines 35-39)

Regarding claim 17, Onodera et al. discloses the filter membrane is designed for use in separating an undesired substance from whole blood or plasma. (See Col 3, lines 25-30) Onodera et al. discloses the filter medium may comprise a hollow fiber. (See Col 4, all) While applicant does not use the term "precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) Therefore, Onodera et al. teaches a precursor substrate. Kozawa et al. discloses the semipermeable membrane (i.e. hollow fiber membrane) may be used as an artificial kidney. (See Col 4, lines 1-5 and 17-23)

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbell et al. (US 2002/0128234) discloses multifunctional, polyionic copolymers with molecular architectures and properties optimized for specific applications are synthesized on/or applied to substrate surfaces for analytical and sensing purposes. (See Abstract)

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTREV C. SYKES whose telephone number is (571)270-3162. The examiner can normally be reached on Monday-Thursday, 8AM-5PM EST, alt Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on 571-272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela Ortiz/
Supervisory Patent Examiner, Art Unit 1780

/ACS/
Examiner
10/18/10